IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

GALDERMA LABORATORIES, L.P., *et al.*,	)	
	)	Redacted:
Plaintiffs,	)	Public Version
	)	
v.	)	C.A. No. 17-1783-RGA
	)	
TEVA PHARMACEUTICALS USA, INC.,	)	[redacted]
	)	
Defendant.	)	

DEFENDANT'S REPLY POST-TRIAL BRIEF REGARDING INVALIDITY OF PATENT NOS. 9,089,587, 9,233,117 AND 9,233,118

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Galderma completely ignores the construction of "significant reduction/improvement"—"a reduction/improvement that is statistically significant, ***not due to chance alone,*** which has a p-value of 0.05 or less." D.I. 126 at 2. There is no requirement that this element be met by "a randomized blinded study with a comparator." Galderma's Resp. Brief ("Resp. Br.") 6. Rather "if something works," then "it would show statistical significance." Tr. 492:22-493:14, 559:18-560:22 (RG). Confirming effects that exist in the prior art through established testing procedures simply is not inventive. *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1380 (Fed. Cir. 2001); *Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344, 1354 (Fed. Cir. 2012).

I. THE ASSERTED CLAIMS ARE ANTICIPATED BY MANETTA

Manetta claim 1 is a regimen (repeated application) for treating skin affected by rosacea (pimples being the most common symptom) with Soolantra.[1] By definition, "rosacea" in Manetta is characterized by, *inter alia*, papules and pustules; most rosacea patients have PPR, and effective topical rosacea treatments at the time were for PPR. D.I. 126 at 2; Tr. 503:4-19 (RG). A POSA would "reasonably understand or infer" (*In re Baxter Travenol Labs.*, 952 F.2d 388, 390 (Fed. Cir. 1991)) Manetta's "treatment of rosacea" includes treating "lesions ***of rosacea***."[2] Additionally, Parks' treatment of "acne rosacea," "acneiform pustules," and "stubborn condition of acne" clearly discloses topically treating rosacea lesions with ivermectin. DX-15; Tr. 508:7-20 (RG). Galderma offers no substantive response.[3]

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[1] Galderma misstates Dr. Gallo's testimony as "treating rosacea would not necessarily treat PPR," Resp. Br. 10 (citing Tr. 589:22-590:12), and thus that Manetta does not disclose treating PPR. Dr. Gallo made no such statement. He actually said there are *now* approved drugs which "act to prevent some of the vasodilation, so it's preventing a symptom of rosacea." Tr. 589:22-590:12 (RG).

[2] Even if Manetta did not anticipate treatment of PPR, it would be obvious to treat PPR. *See Prometheus v. Roxane*, 805 F.3d 1092, 1101 (Fed. Cir. 2015) (obvious to use drug to treat particular type of disease where prior art taught treatment of general disease with same drug).

[3] If there were any doubt as to how a POSA would understand "acne rosacea" as used in Parks,

Galderma argues Manetta does not teach once daily treatment because "regimen" might encompass a number of "potential dosing frequencies." Resp. Br. 11. No matter—a POSA envisages once daily. In 2012 all FDA-approved topicals for rosacea were used once or twice daily. Tr. 471:10-21, 504:1-5, 504:8-12 (RG); Tr. 317:21-318:3 (TP). This common knowledge is not "additional prior art," Resp. Br. 11; "extrinsic evidence may be considered when it is used to explain, but not expand, the meaning of a reference." *In re Baxter*, 952 F.2d at 390. Here, a POSA reading "regimen for the treatment of rosacea" would understand Manetta teaches once daily treatment of lesions, at least by considering known application frequencies as well as Parks' once a day treatment, explicitly disclosed through incorporation. DX-15; Tr. 509:12-18 (RG). Galderma criticizes its Parks patent as using "at least" a lower dose, applied once daily followed by maintenance therapy. Yet the fact remains that Parks expressly teaches once daily application, and Manetta sought to make an industrial version of Parks' effective treatment. DX-8, 1:63-2:10. Galderma argues that using the composition of Manetta once daily followed by maintenance therapy would not achieve the claimed efficacies. Resp. Br. 11. But the patents-in-suit say Manetta's composition "can be used in the present invention" (PX-1 8:50-55) and the claims only require once daily application, not for a specified period of time. Parks' file history confirms his treatment worked within 2 weeks and better than metronidazole.[4] DX-74.0015-17. Galderma's contrived suggestion that if Manetta were applied a single time, or once a week, it would not necessarily achieve any of the claimed efficacies belies the standard of treatment—a POSA knew to treat until there is a response. Resp. Br. 12. Practicing Manetta claim 1 necessarily achieves the claimed "efficacies" as they have been shown to "not [be] due to chance alone." D.I. 126; Teva's

the file history of Parks makes clear that it refers to PPR. DX-74; Tr. 515:23-516:12 (RG).

[4] As for Parks using a lower dose than Manetta, Dr. Gallo testified that it would be "a terrible idea" to go to a dosing schedule of less than once daily. Tr. 510:4-14 (RG).

Opening Brief ("Op. Br.") § IV.C. Galderma does not dispute that, used once daily, Manetta necessarily achieves the claimed efficacies.

Galderma does not credibly contest that a POSA would use the compositions of Manetta once daily, but instead makes an irrelevant point that other application frequencies might also work. Resp. Br. 14. Topical treatments for PPR at the time were applied once or twice daily, and once daily was more desirable because it encourages patient compliance. Tr. 502:15-17 (RG); Tr. 679:8-12, 679:21-680:1, 690:17-25 (GW); Tr. 629:7-11 (RT); PX-53 at 181857 ("compliance is…enhanced by a once daily treatment."); DX-8, cl. 1. Manetta anticipates because it "placed the public in possession" of an embodiment of the Asserted Claims. *In re Donohue*, 766 F. 2d 531, 533 (Fed. Cir. 1985) ("Such possession is effected if a [POSA] could have combined the publication's description of the invention with his own knowledge to make the claimed invention.").

II. THE ASSERTED CLAIMS ARE OBVIOUS OVER THE PRIOR ART

Confronted with an overwhelmingly clear obviousness case—using Manetta's prior art formulation (1) for its intended purpose and (2) in the way that 1% topical ivermectin was being used in the Clinical Trial Publications (Op. Br. 9)—Galderma musters myriad reasons why Teva's combination is improper. None hold weight.

Galderma argues that Teva fails to prove a motivation for using topical ivermectin to treat PPR, stating that "substantial evidence discouraged pursuit of such a method," Resp. Br. 15, and later repackages the same arguments to argue that "uncertainty" about "the specific cause(s) of PPR, the role of *Demodex*, and ivermectin's mechanism of action" negates an expectation of success. Resp. Br. 24. While these arguments sound remarkably like "teaching away" or "skepticism of others," a secondary consideration which Galderma agreed it was not asserting, Tr. 750:10-12, they are also contrary to the evidence. "A finding that the prior art as a whole suggests the desirability of a particular combination need not be supported by a finding that the prior art

suggests that the combination claimed ... is the preferred, or most desirable, combination." *Bayer Healthcare Pharm., Inc. v. Watson Pharm., Inc.*, 713 F.3d 1369, 1376 (Fed. Cir. 2013); *see also Bayer Pharma AG v. Watson Labs., Inc.*, 874 F.3d 1316, 1328 (Fed. Cir. 2017) ("obviousness does not require that the motivation be the best option, only that it be a suitable option from which the prior art did not teach away") (quotations omitted). Indeed, the prior art is replete with references disclosing successfully treating PPR with ivermectin, including topical, and ***none*** showing it to be ineffective. *See* DX-8; DX-15; DX-16; DX-67; DX-74; DX-120; Tr. 470:5-23, 473:16-474:10, 475:7-13, 476:11-478:13, 479:1-14, 479:24-480:4 (RG). And knowing its specific biochemical mechanism of action is unnecessary to motivate treatment with ivermectin; Soolantra's label indicates it was approved without mechanistic proof. PX-35 at 513. *Alcon Research, Ltd. v. Apotex Inc.*, 687 F.3d 1362, 1368 (Fed. Cir. 2012) (motivation need not be the same as patentee's).

Nor is Teva engaging in hindsight by using Galderma's published art and choosing Manetta composition 5 (i.e., claim 1). Resp. Br. 17. The RSG publications explicitly combine the clinical trial studies with Manetta—the combination is public. DX-70.3. Moreover, a POSA would choose Manetta composition 5 due to its declared "very good chemical stability" and superior human tolerability. DX-8, 10:22-11:19 (Examples 8-10); Tr. 507:9-24, 513:17-514:23, 607:6-22 (RG); Tr. 644:23-645:13, 679:18-20; 694:10-14 (GW).[5] Teva also explained why a POSA would choose once daily application given better compliance and the Clinical Trial Publications teaching 1% ivermectin topical use once daily. Op. Br. 21-24.

Galderma argues that the Asserted Claims are not obvious over Manetta because there must be a reasonable expectation of success in achieving the claimed efficacies, and incorrectly suggests Teva is using inherency as a substitute for an expectation of success. Resp. Br. 14-15. Inherency

[5] Galderma's patents-in-suit state all the formulations of Manetta would work. PX-1, 8:51-56.

does apply to obviousness, as here, where a property is necessarily present in the prior art combination.[6] *See Alcon*, 687 F.3d at 1369; *In re Huai-Hung Kao*, 639 F.3d 1057, 1070 (Fed. Cir. 2011); *see also In re Kubin*, 561 F.3d 1351, 1357 (Fed. Cir. 2009). The claimed efficacies are simply "[n]ewly discovered results of known processes directed to the same purpose[, which] are not patentable because such results are inherent."[7] *Ben Venue*, 246 F.3d at 1376; *see also Abbott Labs.*, 471 F.3d at 1368 ("The general principle that a newly-discovered property of the prior art cannot support a patent on that same art is not avoided if the patentee explicitly claims that property" (internal quotation marks omitted)); *Santarus*, 694 F.3d at 1354 ("obvious formulation cannot become nonobvious simply by administering it to a patient and claiming [the result]"). Because the claimed efficacies are inherent properties that necessarily flow from using Manetta claim 1 (treating with formulation of Soolantra), Teva need only prove that a POSA would have a reasonable expectation that practicing the steps of the claimed method would achieve the claimed invention, i.e. that topically applying Manetta (1% ivermectin) once daily to inflammatory lesions of rosacea would reduce the number of lesions.[8]

Galderma also argues that Teva misapplies reasonable expectation of success, pointing to *Sanofi v. Glenmark Pharm. Inc. USA*, 204 F. Supp. 3d 665, 691-698 (D. Del. 2016). However, that

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[6] Inherency for obviousness is only inappropriate when the inherent properties are unexpected. *See Honeywell Int'l Inc. v. Mexichem Amanco Holding S.A. DE C.V.*, 865 F.3d 1348, 1355 (Fed. Cir. 2017) ("What is important regarding properties that may be inherent, but unknown, is whether they are unexpected."); *Pernix Ireland Pain DAC v. Alvogen Malta Ops. Ltd.*, 323 F. Supp. 3d 566, 606-7 (D. Del. 2018). Here, there are no unexpected results as Galderma is only asserting commercial success as a secondary consideration. Tr. 750:10-12.

[7] Galderma now describes the claimed efficacies as "unexpected," Resp. Br. 2, but is not asserting "unexpected results." Tr. 750:10-12.

[8] In fact, Galderma does not differentiate between reducing lesions and the other claimed efficacies. *See* D.I. 241 ("Gal. Br.") at 17 (arguing that meeting claim 6 of the '118 patent alone establishes satisfying all of the Asserted Claims).

case did not deal with inherent properties like those here. There is no legitimate question that at the very least a POSA would have expected success in achieving a statistically significant reduction in lesion count, i.e., that ivermectin would work. Dr. Webster said so in the prior art. Tr. 665:24-666:2 (GW). Galderma's *post-hoc* rationalization is based not on testimony but on Galderma rewriting the facts. In response to a statement that topical ivermectin works, Dr. Webster stated, "topical lindane doesn't do much." DX-243.0011. He never contradicted the fact that ivermectin was known to work; he simply thought it might be as an anti-inflammatory rather than through killing mites. *Id.* at 11, 24. In fact, he did the opposite, twice confirming that "ivermectin works." DX-243.0024; Tr. 665:19-666:2 (GW). And Dr. Webster correctly predicted that three rosacea products would work, further illustrating that in topical dermatology there is a high success rate in phase III. DX-243.0023-24; Tr. 670:25-671:3 (GW).

Galderma argues there is no reasonable expectation of success (1) because the prior art did not disclose statistically significant results and (2) due to the supposed problems with each individual prior art reference. Resp. Br. 19-24. But what matters is simply whether there was an expectation of success in achieving results "not due to chance alone," which is all that statistical significance requires. D.I. 126 at 2. And "one cannot show non-obviousness by attacking references individually where, as here, the rejections are based on combinations of references." *In re Keller*, 642 F.2d 413, 426 (C.C.P.A. 1981). A reference "must be read, not in isolation, but for what it fairly teaches in combination with the prior art as a whole." *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). The prior art as a whole establishes a reasonable expectation of success in achieving each of the claimed efficacies. Op. Br. § IV.D.2.b. For instance, Parks disclosed that topical ivermectin worked for PPR as early as two weeks, worked where

metronidazole failed, and achieved "prolonged remission." Tr. 516:20-518:2 (RG).[9] The Clinical Trial Publications disclosed large scale studies with the very same clinical endpoints as claimed in the Asserted Patents. Op. Br. 22 n.8, 28-29. As Dr. Plott explained, a POSA would have a reasonable expectation of success given Galderma's progression into three large, simultaneous, phase III studies; two versus vehicle and a third versus the "gold standard" metronidazole, requiring comparison to another approved treatment. Tr. 338:6-21, 341:24-343:9 (TP). It would be unreasonable to do both studies simultaneously unless there was a high likelihood of success.

III. THE ASSERTED CLAIMS ARE ANTICIPATED BY MCDANIEL

McDaniel discloses: (1) "[a] method of treating rosacea" (DX-16.3, cl. 1); (2) in patients with "papules and pustules" (*id*. 3:38, 3:52, 4:8-9); (3) by topically applying to the affected skin area (*id*., cl. 1, 5); (4) 1% ivermectin in a "lotion, cream or gel" (*id*.); (5) "at least once" daily (*id*., cl. 8); (6) "for a period of about two" weeks (*id*.). McDaniel's treatment *is* directed to the "same purpose or use" as the Asserted Claims: using ivermectin to treat PPR. McDaniel uses the same method as the Asserted Claims to achieve this purpose. Op. Br. 10-12. Unlike certain claims in *Perricone*, 432 F.3d at 1379, where treatment of sunburn was "not analogous to skin surfaces generally," McDaniel specifically discloses the same treatment both generally and specifically. There is no dispute that papulopustular rosacea is rosacea[10] (DX-118.1) and the examples in McDaniel state patients had PPR (DX-16, 3:27-29, 43-45, 55-60), unlike in *Rapoport* and *Glaxo Group* (Resp. Br. 7, n.39) where the prior art use and claimed use were for distinct conditions.

Galderma misreads McDaniel's disclosures on *Demodex* and co-administration. Resp. Br.

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[9] The file history of Parks states that Parks submitted a declaration to demonstrate earlier reduction to practice than McDaniel; hence Parks was required to show representative examples antedating McDaniel, not every patient example. DX-74.0010, 13-14, 20, 22.

[10] Galderma misquotes Dr. Gallo (Resp. Br. 8, n. 48). He testified that "at that time" (i.e. 2012), there were no drugs that treated rosacea but not PPR or lesions of rosacea. Tr. 589:22-590:1.

4. McDaniel's claims and teachings do not require co-administration of ivermectin with any drug. DX-16.3, cls. 1, 5, 8. In fact the "coadministered drug" had been shown not to work on the relevant patients. DX-16.3, 3:24-27, 4:1-3; Tr. 493:19-494:10 (RG). Nor does McDaniel indicate that ivermectin "elicits lesion formation"; rather a POSA reading the full quote would understand that the ivermectin was working. DX-16, 2:51-55; Tr. 558:6-15, 583:17-24 (RG). McDaniel explicitly discloses applying topical ivermectin for 2 weeks to "treat[] rosacea," *id*. cl. 8, and explicitly teaches that treatment using topical ivermectin will, like the oral examples, be an "effective treatment for rosacea." DX-16.3, 4:12-23; Tr. 473:19-24, 486:13-19, 489:12-20, 493:7-14 (RG).

For the first time in this case, without any supportive testimony, Galderma alleges that McDaniel's 1-5% range is not "sufficiently specific." Resp. Br. 4-5. This argument should be stricken because it is prejudicially late, as it was not presented in Galderma's issues of fact or law or at trial, and because McDaniel discloses a sufficiently narrow range of percentages of ivermectin. Furthermore, as Galderma has "not argued that the [dosage] limitation…is 'critical,' or that the claimed method works differently at different points within the prior art range," McDaniel's disclosure anticipates the use of 1% ivermectin. *ClearValue, Inc. v. Pearl River Polymers, Inc.*, 668 F.3d 1340, 1345 (Fed. Cir. 2012) (distinguishing *Atofina*).[11]

Galderma has stipulated that "Manetta enables McDaniel in 2012 as to the formulation." D.I. 219 at 12. As part of this stipulation, Mr. Alibhai agreed that Manetta was "enabling the claims of McDaniel." Appendix I, 191:17-19. Galderma is attempting to renege on its stipulation, stating that McDaniel's "undisclosed formulation" would not necessarily achieve the claimed efficacies.

[11] *Impax*, 246 F. Supp. 3d at 1035 (Resp. Br. 5 n.20), dealt with pH ranges on a logarithmic scale, unconnected from the drug at issue. *Atofina*, 441 F.3d at 999 (Resp. Br. 5 n.20), dealt with a temperature range of over 100 degrees; here, McDaniel discloses a "very small genus" (*id.*), including 1% ivermectin explicitly.

Resp. Br. 8-9. McDaniel is presumed enabled, and Galderma has not offered testimony from any witness to support its new theory or to overcome this presumption. Op. Br. 3. Because McDaniel is enabled as to its claims and disclosures, McDaniel will obtain the claimed results.

Galderma also fatally misrepresents Teva's burden on anticipation. Teva need not show that ***all*** 1% ivermectin formulations would necessarily achieve the claimed efficacies, or that McDaniel enables ***all*** such formulations.[12] *Contra* Resp. Br. 7. "[T]he reference need only enable a single embodiment of the claim." *In re Morsa*, 803 F.3d 1374, 1377 (Fed. Cir. 2015); *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1562 (Fed. Cir. 1991) ("the description of a single embodiment of broadly claimed subject matter constitutes a description of the invention for anticipation purposes"). As stipulated, McDaniel is enabled as to its formulations and claims by Manetta, and therefore will achieve the claimed results—Teva has met its burden of proof.

McDaniel teaches that its method of treatment "works" as described, and better than "any previously described method," including metronidazole.[13] (Op. Br. 13-16). McDaniel is "getting an investigator global assessment," and "counting papules" with "three patients that started with rosacea and ended improved," and is "say[ing] topical would work."[14] Tr. 569:15-22, 570:3-22, 571:22-572:1 (RG). Because McDaniel's treatment works, the improvement/reduction is not due

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[12] The question of whether *a single* composition claimed by McDaniel will inherently anticipate is a separate issue from whether Teva's *particular* ANDA product infringes. *Contra* Resp. Br. 8 n.50 (citing *Hospira*, 285 F. Supp. 3d at 800). The quoted testimony of Drs. Amiji and Gallo used by Galderma is a mishmash of statements made with respect to written description (a requirement extending to the *full scope* of the Asserted Claims) and infringement (considering Teva's particular ANDA product). Resp. Br. 8. In fact, McDaniel's method explicitly claims a 1% ivermectin lotion, cream, or gel, providing *more* detail as to the composition than the Asserted Claims, which are directed to any 1% ivermectin pharmaceutical composition.

[13] *In addition to* the working example comparing to metronidazole (Op. Br. 15), there "is no requirement for examples" for Dr. McDaniel's claims to be sufficiently enabled. Resp. Br. 27.

[14] Galderma twists Dr. Gallo's testimony (Resp. Br. 8 n.49); he testified "it's actually possible to get highly significant, believable results with small sample sizes." Tr. 568:16-569:3 (RG).

to chance alone.[15] As Dr. Betensky testified, a significant result "means that there is evidence that that result did not arise from chance alone, but that truly reflects some effect, some drug difference or drug effect." Tr. 383:1-7 (RB). McDaniel teaches reducing lesions, as early as two weeks, and working better than metronidazole and therefore anticipates the claims. *Donohue*, 766 F. 2d at 533.

IV. THE ASSERTED CLAIMS LACK WRITTEN DESCRIPTION

Galderma conflates enablement with written description. Here, the question is whether the patent provides evidence to a POSA that the inventors possessed the full scope of the claims, covering 17 dosage forms[16] and achieving the claimed efficacies. The simple answer is no. While the claims encompass thousands of formulations that *might* achieve the claimed efficacies, each would require testing to determine. Tr. 693:1-694:6 (GW); Tr. 282:22-283:4, 313:4-18 (MA); Tr. 381:14-18, 382:1-7 (RB). Therefore, the patents require more specificity to ensure the inventors invented "not simply a single operative embodiment within that class." *Pernix*, 323 F. Supp. 3d at 625-626.[17] As in *Ariad*, 598 F.3d at 1353, Galderma invited the POSA to experiment to determine which formulations get the claimed efficacies with the promised reward of an infringement suit. The claims are invalid for lack of written description.

For the forgoing reasons, the Court should find all Asserted Claims invalid.

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[15] Even if the Court determines the claimed efficacies are limitations, as in *Ben Venue*, McDaniel performs "all the steps of the [] claims at issue," including the efficacies. 246 F.3d at 1378.

[16] Galderma ignores that the claimed "pharmaceutical composition" covers 17 dosage forms, instead implicitly asking the Court to limit the claims to "cream, lotion, or gel" forms. Resp. Br. 28. But "Courts do not rewrite the claims to narrow them for the patentee to cover only the valid portion." *Alcon*, 687 F.3d at 1368.

[17] Galderma relegates *Pernix* to a footnote because it "is at odds with *Alcon*…" and is on appeal. Resp. Br. 29 n.190 (citing *Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180 (Fed. Cir. 2014)). Judge Bryson wrote the *Pernix* opinion aware of *Alcon*: he cites *Alcon*, and was on the panel in *Alcon*. Here, unlike in *Alcon*, the claims recite particular efficacies, and a POSA would not have understood that the inventors invented the claimed methods. Tr. 693:1-694:6 (GW); Tr. 282:22-283:4, 313:4-18 (MA); Tr. 381:14-18, 382:1-7 (RB); Tr. 627:7-20 (RT).

Respectfully submitted,

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Dated: July 1, 2019

APPENDIX I

Redacted In Its Entirety

CERTIFICATE OF SERVICE

I, Karen E. Keller, hereby certify that on July 1, 2019, this document was served on the persons listed below in the manner indicated:

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